

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 23, 2009 has been entered.

### ***Response to Amendment***

2. This office action is responsive to the amendment filed on October 23, 2009. As directed by the amendment: claims 1 and 12 have been amended, claim 11 has been cancelled, and new claims 17-19 have been added. Thus, claims 1-10 and 12-19 are presently pending in this application.

### ***Claim Objections***

3. Claims 1-6, 9, 10, 16, and 19 are objected to because of the following informalities:

4. Regarding claim 1, "both pistons" and "the two pistons" lack antecedent basis; "the active agent" and "the gas" lack antecedent basis; "one of the chambers" lacks antecedent basis. It is recommended to amend claim 1 (and the other claims listed below) so that language used to initially recite elements is consistent throughout the claims.

Art Unit: 3763

5. Regarding claims 2, 9, and 10, "the active agent" and "the gas" rely upon a parent limitation that lacks antecedent basis.
6. Regarding claim 3, "one of the two pistons" lacks antecedent basis.
7. Regarding claim 4, "the feed channel", "the chamber opened by the connecting element" and "the other chamber" lack antecedent basis.
8. Regarding claim 5, "the chambers" lacks antecedent basis.
9. Regarding claim 6, "one of the two pistons" lacks antecedent basis.
10. Regarding claim 10, "the feed channel" lacks antecedent basis.
11. Regarding claim 16, "one after the other" lacks antecedent basis.
12. Regarding claim 19, "at least opening" seems to be grammatically incorrect. For the purposes of examination, Examiner assumes, given the singular use of "opening", that the intended language is "at least *one* opening".
13. Appropriate correction is required

***Claim Rejections - 35 USC § 112***

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
15. Claims 1, 4, and 6-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
16. Regarding claim 1, the limitation "wherein both pistons *may be interconnected...*" is indefinite because it is unclear whether the language is indicating that interconnection is optional language, functional intended use language, or whether interconnection is

Art Unit: 3763

intended to be positively recited. Examiner interprets “may be” as optional language, but claim 1 goes on to recite the limitation “wherein the two pistons are interconnected” which seems to be counterintuitive to the previous limitation. It is recommended to amend the limitation “may be interconnected” to positively recite interconnection, or to amend the claim and its dependents so that it is clear that interconnection is optional.

17. Regarding claims 1, 4, and 6-9, it appears that claim element “foam producing means” is intended as a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, it is unclear whether the claim element is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph, because it does not include the full phrase “means **for**”. If applicant wishes to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant is required to:

(a) Amend the claim to include the phrase “means for” or “step for” in accordance with these guidelines: the phrase “means for” or “step for” must be modified by functional language and the phrase must **not** be modified by sufficient structure, material, or acts for performing the claimed function; or

(b) Show that the claim limitation is written as a function to be performed and the claim does **not** recite sufficient structure, material, or acts for performing the claimed function which would preclude application of 35 U.S.C. 112, sixth paragraph. For more information, see MPEP § 2181.

18. Further, regarding claims 7 and 8, the claim limitation “foam producing means” uses the phrase “means for” or “step for”, but it is modified by some structure, material, or acts recited in the claim. If the issues discussed in par. 5 above are resolved, claims

Art Unit: 3763

7 and 8 would appear to be modified by sufficient structure ("has a foam exit opening..."; "includes at least one sieve...") to preclude the invoking of 35 U.S.C. 112, 6<sup>th</sup> paragraph in these claims.

***Claim Rejections - 35 USC § 102***

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. Claims 1-10, 12-14, 16, and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Herman (US 4014463).

21. Regarding claims 1-10, 12-14, 16, and 17-19, Herman discloses a device for producing medicinal foam (see fig. 1), comprising an active agent chamber 12 closed with a first piston 18; a gas chamber 16 closed with a second piston 14 and closed with the first piston (see fig. 1), the gas chamber and the active agent chamber being arranged one after another (see fig. 1), and a foam producing means (mixer 48) connected with the active agent chamber and the gas chamber (see fig. 1), wherein both pistons may be interconnected and displaced in common (see fig. 1; displacement of 14 also displaces 18) to cause a pressure increase both in the active agent chamber and the gas chamber and to feed the active agent and the gas to the foam producing means (col. 4, ln. 15-35), and wherein the two pistons are interconnected through a connecting element in the form of a hollow needle 30 which opens one of the chambers when it is displaced; openings defined through the second piston (openings defined

Art Unit: 3763

near 40 and 34 elements on fig. 1); the connecting element comprises a feed channel 46; an entrainment element 36 for entraining one of the two pistons, rigidly connected to the hollow needle between the first and second pistons (see fig. 1) in a position offset from the open end of the hollow needle (see fig. 1), upon displacement of the second piston to a point where the hollow needle pierces through the first piston (such as shown in fig. 1) and the entrainment element contacts the first piston (fig. 1), the entrainment element maintains a distance between the first and second pistons to allow a pressure increase in both chambers (see fig. 1 and col. 4, ln. 15-35; element 36 allows 14 and 18 to move in unison while applying pressure to both chambers); the feed channel connects the chamber opened by the connecting element immediately with the foam producing means (see fig. 1); the chambers adjoin each other (see fig. 1); the foam producing means has a foam exit opening 80 and a sieve 52; a slow-down element 26; the connecting element has openings (on either end, see fig. 1); the foam producing device is removably connected to the second piston by a holder (holder 58, mutually connected with second piston to element 10) comprising a foam exit opening (centrally located passageway of 58).

### ***Claim Rejections - 35 USC § 103***

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3763

23. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Herman in view of Chu (US 4743229).

24. Regarding claim 15, Herman discloses the apparatus as claimed except for a Luer. However, Chu teaches use of a Luer to connect a mixing device to a syringe (see fig. 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize a Luer fitting as taught by Chu for the purpose of permitting interaction with a wide range of devices.

### ***Response to Arguments***

25. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN R. PRICE whose telephone number is (571)270-5421. The examiner can normally be reached on Monday-Thursday, 9:00 a.m. - 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. R. P./  
Examiner, Art Unit 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art  
Unit 3763